DEC 0 6 2002

K023219

510K Summary of Safety and Effectiveness

1. **Submitted By:**

John Schalago
Manager, Regulatory Affairs

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Phone: 201-847-5663
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2. **Device Name:**

Trade Name:	BD™ Diabetes Software
Common Names:	Blood Glucose Meter and Data Management System
Classification Name:	Glucose test system
Classification:	862.1345

3. **Predicate Device:**

WinGlucofacts

Manufactured by: Bayer Diagnostics

4. **Device Description:**

BD™ Diabetes Software is data management software intended for use with BD Blood Glucose Monitoring Systems only. The software is designed to operate on a Windows/Intel compatible platform, and is available in home use and professional use options. Data may be downloaded from a BD Blood Glucose Monitor or manually entered.

BD™ Diabetes Software provides data management tools for acceptance, transfer, display, storage, processing (*e.g.* averaging), reporting, and printing of patient blood glucose monitoring data. In addition, the BD™ Diabetes Software has an online help feature.

510K Summary of Safety and Effectiveness (*Continued*)

5. **Intended Use:**

The BD™ Diabetes Software is intended for use as a data management tool for acceptance, transfer, display, storage, processing (*e.g.* averaging), reporting, and printing of patient blood glucose monitoring data.

The device is intended for use with a BD Blood Glucose Monitoring System only.

6. **Technological Characteristics:**

The BD™ Diabetes Software is a Microsoft Windows based software application for diabetes data management. The software allows for data transfer from a BD Blood Glucose Monitor via a BD Interface serial or USB cable. BD™ Diabetes Software is designed to operate an Intel compatible PC with Microsoft Windows 95 or later, and Microsoft NT version 4.0 or later operating system.

7. **Performance Summary:**

BD™ Diabetes Software testing consisted of system, hardware, software, packaging, electrical safety, and end-user evaluation. System verification and validation activities demonstrate that BD™ Diabetes Software will perform as intended when used in accordance with device labeling. Electrical components have been tested and certified to conform to appropriate voluntary and mandatory standards.

The term "substantial equivalence" as used in this 510(k) Notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-approval or classification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 6 2002

Mr. John A. Schalago MS, RAC
Regulatory Affairs Manager
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

Re: k023219
Trade/Device Name: Becton Dickinson Diabetes Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; JQP
Dated: September 18, 2002
Received: September 26, 2002

Dear Mr. Schalago:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Attachment XI .A.1

510(k) Number (if known):_____

Device Name: Becton Dickinson Diabetes Software

Indications For Use:

The BD™ Diabetes Software is intended for use as a data management tool for acceptance, transfer, display, storage, processing (*e.g.* averaging), reporting, and printing of patient blood glucose monitoring data.

The device is intended for use with the BD Blood Glucose Monitoring Systems only.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023899

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)